Remarks

The oath or declaration is objected to. Applicant requests that this requirement be held in abeyance as it attempts to collect the properly executed documents from former employees.

Rejection of Claims 1-4, 6, 7, 20-39, 41, 42, 46-48 under 35 U.S.C. § 1112, first paragraph.

Claims 1-4, 6, 7, 20-39, 41, 42, 46-48 are rejected as not fully enabled under 35 U.S.C. § 1112, first paragraph. The U.S. Patent and Trademark Office acknowledges that a method of modulating calcium channel activity in a rodent heart comprising administering locally to the heart an adenovirus comprising a nucleic acid that encodes the human guanosine triphosphatase (GEM) protein. However, it urges that unpredictability in the art of gene therapy prevent the extrapolation from the rodent experiments of the specification to all mammals.

The U.S. Patent and Trademark Office acknowledges the working examples which demonstrate operability in both mouse and guinea pig, two species of mammal, but cites references which purportedly demonstrate unpredictability. The references do not, however, speak to unpredictability in moving from rodents to other mammals.

- Concalves is cited as teaching that viruses have resulted in significant unpredictability, with retroviruses and adenoviruses providing only a fleeting success that was ultimately undone by a lack of transduction and low transgene expression levels. This teaching does not address an inability to exptrapolate from mouse and guinea pig to other mammals.
- Parekh-Olmedo is cited as teaching that gene repair using gene therapy with single-stranded oligonucleotides is unpredictable. The present invention does not employ single-stranded oligonucleotides to perform gene repair. Parekh-Olmedo's cited teaching does not address exptrapolation from mouse and/or guinea pig to other mammals.
- Verma is cited as teaching obstacles to transduction including the production of the vector, the targeting of the vector to a specified cell type, sustained gene expression, and avoidance of insertional mutagenesis and immune responses. None of these potential issues prevents one of skill in the art from extrapolating from the successful working examples in laboratory animals to other mammals.

- Fishbein is cited as teaching delivery challenges to the heart. The working examples of the present invention, however, teach successful delivery to the heart. Moreover, Fishbein's teaching does not address the extrapolation from successful animal models to other mammals.

The U.S. Patent and Trademark Office failed to recognize that the working examples also report successful results in pigs (25-30 kg domestic swine; porcine) in Example 3. Pigs are not rodents. This additional species of mammal further supports applicants claim for enablement of the full species of mammals. No evidence or reasoning has been put forward why the techniques of the present invention would work in pig but not in other mammals.

The U.S. Patent and Trademark Office has not presented any reasons to doubt that the successful practice of the present invention in mouse, pigs, and guinea pigs would also occur in other mammals. Thus, no *prima facie* case of lack of enablement has been made. Withdrawal of this rejection is respectfully requested.

The Rejection of Claims 7, 20, and 30 Under 35 U.S.C. § 112, second paragraph

Claims 7, 20, and 30 stand rejected under 35 U.S.C. § 112, second paragraph. Claim 7 has been cancelled, rendering its alleged lack of clarity moot. Claims 20 and 30 have been amended to address the issues raised by the U.S. Patent and Trademark Office. Withdrawal of this rejection is therefore respectfully requested.

Respectfully submitted,

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